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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/082,492

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Gene Samson

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CROMPTON, SEAGER & TUFTE, LLC
1221 NICOLLET AVENUE
SUITE 800
MINNEAPOLIS, MN 55403-2420

EXAMINER

ARAJ, MICHAEL J

ART UNIT

PAPER NUMBER

3775

MAIL DATE

DELIVERY MODE

12/28/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/082,492	Applicant(s) SAMSON ET AL.	
	Examiner MICHAEL J. ARAJ	Art Unit 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 23, 2009 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In claim 21, line 3 and claim 26, line3, "a connected proximal cage appears to be new matter. "A connected proximal cage" is not defined in the specifications. It is not clear if it is of specific definition or what the proximal cage may be connected to.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 recites the limitation "the proximal cage" in lines 4-5 and 6. There is insufficient antecedent basis for this limitation in the claim.

Claim 26 recites the limitation "the proximal cage" in line 5. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

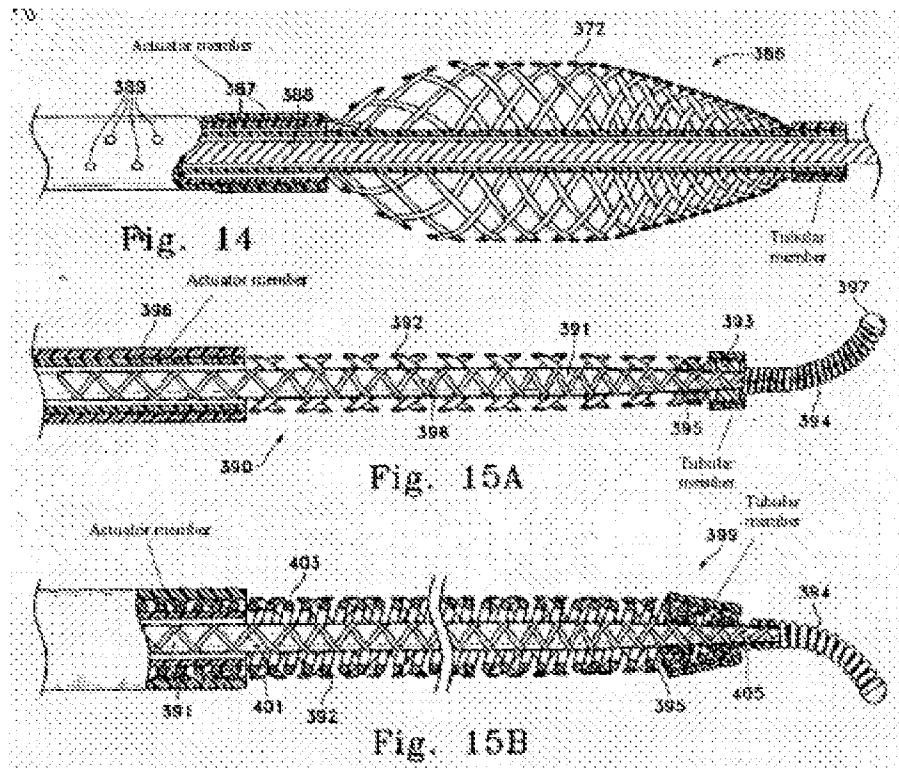
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21, 22 and 24-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Engelson et al. (U.S. Patent No. 5,972,019) in view of Ginsburg (U.S. Patent No. 5,011,488).

Engelson et al. disclose a device comprising a core wire, e.g. 388 01- 391 with a coil tip coupled to a distal end of the core wire (see for example Figures 14, 15A, 15B). The device further comprises a cage, e.g. 372 or 392. The cage has a distal end, proximal end, first deployment shape, and a second expanded shape. The first and second shapes are different from each other. The device further has a tubular member

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(see Figures 14, 15A, and 15B) coupled to a distal end of the cage assembly and the tubular member surrounds a distal portion of the core wire proximal to the coil tip.



The device also has an actuator member, as shown above, that has a first position and a second position, and is located proximally to the cage and substantially coaxial about the core wire. When the actuator member is in a first position the cage is in a deployment shape and when the actuator member is in the other position, the cage is in the second expanded shape. The core wire is freely moveably axially through the cage assembly (see col.13, lines 43-44). The tubular member can be considered a bushing. The device can further include an inner coil, e.g. 401, surrounding the core wire within the cage assembly. The inner coil inner coil does not pass distally on the core wire.

Engelson et al. disclose the claimed invention except for a cage assembly including a proximal cage and a distal cage.

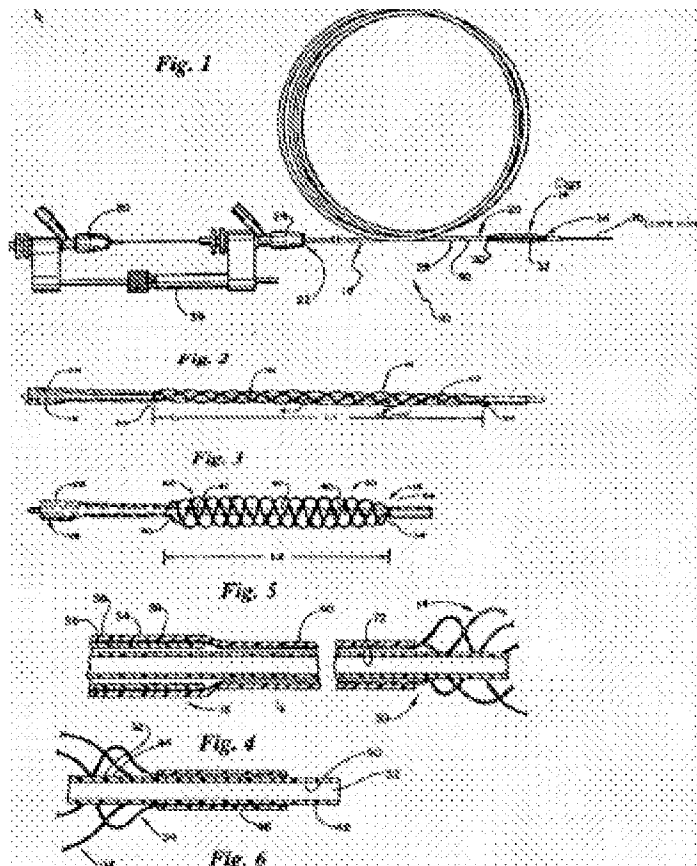
Engelson discloses the claimed invention except for the use of a proximal and distal cage. Ginsburg discloses the use of a proximal and distal element (balloon) in order to remove the thrombotic material without surgical intervention (Col. 7, lines 12-15). The proximal element is connected to the device. It would have been obvious to one skilled in the art at the time the invention was made to construct the device in Engelson with a proximal and distal cage in view of Ginsburg, in order to have a less extensive procedure. Furthermore, since Ginsburg teaches the use of two cages the proximal and distal cages would be able to be expanded by the same actuator element as shown above.

Claims 21-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmaltz et al. (U.S. Patent No. 5,449,372 cited by applicant) in view of Ginsburg (U.S. Patent No. 5,011,488) further in view of Crittenden et al. (U.S. Patent No. 4,719,924).

Schmaltz et al. disclose a device comprising a core wire or guidewire 70, a cage 14, a tubular member 46, and an actuator element 18 (see Figures 1-5 below). The cage 14 has a distal end, proximal end, first deployment shape, and second expanded shape, wherein the shapes are different from each other (see Figures 2 and 3 below). The tubular member 46 is coupled to the distal end of the cage assembly and it would surround a distal portion of the core wire or guide wire (see Figures 1 and 6 below). The actuator element has first and second positions and it is located proximal to the cage and it is substantially coaxial about the core wire (see Figure 1). The core wire or guide

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wire is freely movable axially through the cage (see col. 8, lines 30-35). The core wire or guidewire may be a standard guidewire. The tubular member is considered a bushing and is made of a thermoplastic material, e.g. polyolefin (see col. 7, lines 15-17). The device further includes inner coils or bands, e.g. 40 and 41, made from radiopaque materials (see col. 6, lines 32-34 and 59-64). The inner coils or bands do not pass distally on the core wire.



Schmaltz et al. disclose the claimed invention except for a cage assembly including a proximal cage and a distal cage. Ginsburg discloses the use of a proximal and distal element (balloon) in order to remove the thrombotic material without surgical intervention (Col. 7, lines 12-15). It would have been obvious to one skilled in the art at

the time the invention was made to construct the device in Schmaltz et al. with a proximal and distal cage in view of Ginsburg, in order to have a less extensive procedure. Furthermore, since Ginsburg teaches the use of two cages it is inherent that the proximal and distal cages would be able to be expanded by the same actuator element as shown above.

The combination of Schmaltz et al. and Ginsburg disclose the claimed invention except for the core wire or guidewire having a coil tip at its distal end and a cage assembly including a proximal cage and a distal cage. Crittenden et al. disclose a core wire or guidewire with a coil tip at its distal end (see Figure 2). The core wire or guidewire is steerable wherein the coil tip can be adjusted without requiring removal of the guidewire from the patient (see abstract). It would have been obvious to one skill in the art at the time the invention was made to use with the device of the combination of Schmaltz et al. and Ginsburg with a core wire or guidewire that is steerable instead of one that is not in view of Crittenden et al., so that the guide wire can be adjusted without requiring removal of the guidewire when it is inserted into the patient.

Claims 32-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Engelson et al. (U.S. Patent No. 5,972,019) in view of Ginsburg (U.S. Patent No. 5,011,488) and further in view of Lefebvre (U.S. Patent No. 5,421,832).

The combination of Engelson et al. and Ginsburg, as applied to claim 21, disclose the claimed invention except for the cage including a plurality of petal shaped wires having a distal rake. Lefebvre teaches that helically twisted bands (which resemble the petal shaped wires) are more successful at stopping small blood clots

than when they are not. It would have been obvious to one skilled in the art at the time the invention was made to construct the distal cage of the combination of Engelson et al. and Ginsburg with a plurality of petal shaped wires having a distal rake in view of Lefebvre, in order to have an embolism treatment device that functions better in treating small blood clots.

Response to Arguments

Applicant's arguments filed October 23, 2009 have been fully considered but they are not persuasive. Applicant argues that nowhere does Engelson appear to disclose a cage assembly comprising both a proximal cage and a distal cage. Engelson does not disclose a proximal and distal cage which is why the teachings of Ginsburg are used. Ginsburg teach an advantageous way to use two elements to remove a thrombic material. The underlying theme of both patents is that they function to remove thrombi. The use of a second cage/element allows for a better way to remove the thrombus without it being released to further cause damage to the patient. Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the assembly of Engelson having a plurality of cages (210), since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

The examiner suggest to the applicant to revisit how the applicant is using “a connected proximal cage”. In the remark it appears that the applicant means that the distal cage is connected to the proximal cage. If this is the case, then it is recommended to do so. The applicant's representative is invited to call the examiner for any clarifications as well as to expedite the prosecution of this case.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL J. ARAJ whose telephone number is (571)272-5963. The examiner can normally be reached on M-F 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached on 571-272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Michael J Araj/
Examiner, Art Unit 3775

/Thomas C. Barrett/
Supervisory Patent Examiner, Art Unit 3775